

REMARKS

Applicants respectfully request reconsideration and withdrawal of the outstanding Office Action rejections based on the foregoing amendments and following remarks. Claims 1-28 were pending in the present application. By this Amendment, Applicant has amended claims 24-28 in accordance with Examiner's suggestion in Office Action dated April 10, 2008 and thus, no new search is necessary. The present Amendment does not introduce any new matter and, thus, its entry is respectfully requested.

35 U.S.C. §112, First Paragraph- New matter

Claims 1-28 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the amendment to Claim 1 reciting "use of a buffer or solvent which has an ionic concentration of 100 mmol/l or less and is capable of maintaining a pH above 9.5 during the coating procedure" is not supported by the specification. Applicants respectfully disagree. Support for this amendment can be found on page 11, lines 24-30 where it is disclosed that "the pH-dependent solubility of the morphogenetic protein and the stable coating of the matrix material is dependent upon the ionic concentration of the buffer or solvent used and can be strongly improved by using a buffer or solvent of low ionic concentration. Preferably, said buffer or solvent has an ionic concentration of 150 mmol/l or less, preferably 100 mmol/l or less". Further support can be found on page 12, lines 20-24, where it is disclosed that "it was additionally quite unexpected that the morphogenetic proteins are not solely soluble but also maintain their biological activity

at strongly acidic (below pH 5.2) as well as at strongly basic pH values (above 9.5) which rarely occur under physiological conditions”, and on page 23, lines 14-16 where it is disclosed that “the process provides for selecting and adjusting the pH of the protein solution to a value of 5.2 or lower or 9.5 and higher, also when in contact with the matrix material”. In addition, Example 4 on page 29 indicates high solubility in a buffer, sodium carbonate at 100 mmol/l and pH 10, which corresponds to the buffer or solvent limitations recited in claim 1. Thus, Applicants submit that the limitation to a buffer or solvent which has an ionic concentration of 100 mmol/l or less and is capable of maintaining a pH above 9.5 during the coating procedure is supported by the specification. Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

35 U.S.C. §112, first paragraph- Enablement

Claims 24-28 are rejected under 35 U.S.C. § 112, first paragraph, as not enabling for the full scope of the claims. The Action states that methods reading on therapeutic methods of osteoinduction are enabled, however the “use of the claimed compositions, comprising osteoinductive proteins and a matrix, to treat tissues unrelated to bone” is not enabled by the Specification.

Claims 24-28 have been amended to limit the scope of the claims to methods of osteoinduction as suggested by the Examiner. The present specification provides support that methods of administering morphogenetic proteins in effective amounts to a

patient are well known in the art (see page 1, lines 11-15 and page 4, lines 3 through page 5, line 24 of Specification), thus, one skilled in the art would be able to treat a variety of tissues in addition to bone, as well as diseases and conditions not only specifically in a bone, but also including those tissues and diseases disclosed on page 7, line 31 to page 9, line 16 of the Specification.

Claims 25-27 have been amended to limit the list of body tissues encompassed by the claim. Applicants submit that a method of osteoinduction may be used to treat symptoms or conditions of diseases or abnormal conditions of not only bone, but other tissues and said method is inherently obvious to one of skill in the art of reconstructive surgery. For example, in order to treat an abnormal condition of connective tissue wherein the tissue normally attaches to a bone, however the bone is missing due to an abnormal condition such as injury or disease, the patient is in need of osteoinduction to generate new bone for the attachment of said connective tissue. Further examples may include osteoinduction of skull bone to treat a condition of neural tissue, osteoinduction of an eye socket to treat a condition of the sensory system, osteoinduction of a broken bone in any part of the body to treat a condition of blood vessels, the circulatory system, or cardiac tissue, wherein bone particles and marrow are leaking into the bloodstream, etc. These and other conditions and tissues to be treated are known to those skilled in the art. Applicants submit that claim 24 has been limited to methods of treating a patient in need of osteoinduction, indicated as enabling by the Examiner, and is now allowable. Claims 25-27, depending from claims 1 and 24, relate to methods of

osteoiduction comprising administering the osteoinductive material of claim 1, and are believed to be allowable for the above reasons.

With regard to claim 28, Applicants submit that claim 28 does not encompass a broad scope since the claim is limited to "treating a condition susceptible to monomeric or dimeric morphogenetic protein therapy". Methods of making morphogenetic proteins and administering them in effective amounts to a patient are well known in the art (see page 1, lines 11-15 and page 4, lines 3 through page 5, line 24 of Specification), thus, after reading the present disclosure, one skilled in the art would be able to improve upon said therapy by using the osteoinductive material of claim 1. In the interests of securing an expedited Notice of Allowance, and without acceding to the rejection, claim 28 has been amended to recite "In a method of treating a patient in need of osteoiduction" as suggested by the Examiner.

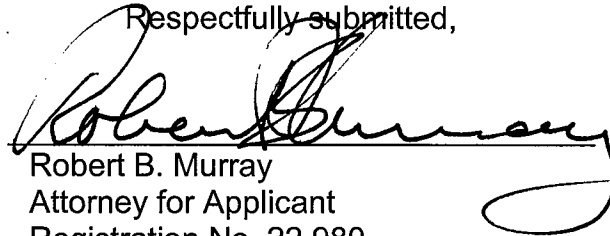
In view of the above amendments and remarks, Applicants believe that all of the Examiner's rejections set forth in the April 10, 2008 Office Action have been fully overcome and that the present claims fully satisfy the patent statutes. Applicants therefore believe that the application is in condition for allowance.

The Director is authorized to charge any fees or overpayment to Deposit Account No. 02-2135.

The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,

By

A handwritten signature in black ink, appearing to read "Robert B. Murray", is written over a horizontal line.

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